



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference CP60859PCT | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/FR2003/003665 | International filing date (day/month/year) 10 décembre 2003 (10.12.2003) | Priority date (day/month/year) 13 décembre 2002 (13.12.2002) |
| International Patent Classification (IPC) or national classification and IPC C12N 1/20, 15/74, C12P 7/56 | | |
| Applicant INSTITUT DE RECHERCHE POUR LE DEVELOPPEMENT (IRD) | | |

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| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>5</u> sheets.</p> |
| <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application |

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| Date of submission of the demand 06 avril 2004 (06.04.2004) | Date of completion of this report 09 February 2005 (09.02.2005) |
| Name and mailing address of the IPEA/EP | Authorized officer |
| Facsimile No. | Telephone No. |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/FR2003/003665

I Basis of the report

1. With regard to the elements of the international application:*

 the international application as originally filed the description:pages 2-13, as originally filed
pages _____, filed with the demand
pages 1,1a, filed with the letter of 03 January 2005 (03.01.2005) the claims:pages 1,2, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____ the drawings:pages _____, as originally filed
pages _____, filed with the demand
pages 1-11, filed with the letter of 03 January 2005 (03.01.2005) the sequence listing part of the description:pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is: the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 contained in the international application in written form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. The amendments have resulted in the cancellation of: the description, pages _____ the claims, Nos. _____ the drawings, sheets/fig _____5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/FR 03/03665

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|-----------|-----|
| Novelty (N) | Claims | 8 | YES |
| | Claims | 1-7, 9-11 | NO |
| Inventive step (IS) | Claims | 8 | YES |
| | Claims | 1-7, 9-11 | NO |
| Industrial applicability (IA) | Claims | 1-11 | YES |
| | Claims | | NO |

2. Citations and explanations

1. Cited documents

D1: DRANCOURT MICHEL ET AL: "16S ribosomal DNA sequence analysis of a large collection of environmental and clinical unidentifiable bacterial isolates." JOURNAL OF CLINICAL MICROBIOLOGY, vol. 38, no. 10, October 2000 (2000-10), pages 3623-30; ISSN: 0095-1137;

D2: FARROW JOHN A E ET AL: "Phylogenetic interrelationships of round-spore-forming bacilli containing cell walls based on lysine and the non-spore-forming genera Caryophanon, Exiguobacterium, Kurthia, and Planococcus." INTERNATIONAL JOURNAL OF SYSTEMATIC BACTERIOLOGY, vol. 44, no. 1, 1994, pages 74-82, ISSN: 0020-7713;

D3: FRUEHLING ANJA ET AL: "Exiguobacterium undae sp. nov. and Exiguobacterium antarcticum sp. nov." INTERNATIONAL JOURNAL OF SYSTEMATIC AND EVOLUTIONARY MICROBIOLOGY, vol. 52, no. 4, July 2002 (2002-07), pages 1171-6, ISSN: 1466-5026;

D5: US-A-6 022 537 (GARCIA JEAN-LOUIS ET AL)

8 February 2000 (2000-02-08).

2.1 The present application does not fulfil the requirements set forth in PCT Article 33(1) because the subject matter of claims 1-6 does not comply with the requirement of novelty defined in PCT Article 33(2).

The subject matter of the application relates to a bacterial strain called *Exiguobacterium lactigenes* sp. nov. which is characterised by the 16S ribosomal RNA sequence thereof, and the use of said strain in the production of lactate.

Document D1 describes the classification of a large collection of bacteria by sequencing the 16S ribosomal RNA thereof.

Clone 18 (filed under the no. AF227839) is 98.2% identical over 1492 nucleotides to the claimed sequence and, as a result, deprives the subject matter of claims 1-3 and 6 of novelty (PCT Article 33(2)). The specification, in claim 1, that the genus of the bacterial strain is *Exiguobacterium lactigenes* does not constitute a real technical feature that would enable said strain to be differentiated from the prior art because such a specification amounts to an arbitrary name given by the inventors.

D2 analyses the 16S rRNA sequences of various bacterial species and compares same with other known species. The 16S rRNA of *Exiguobacterium aurantiacum* is one of the species sequenced and the

sequence thereof is 97.4% identical to the claimed sequence. It follows that said sequence deprives the subject matter of claims 1-3 and 6 of novelty (PCT Article 33(2)).

D3 discloses the 16S rRNA sequences of four different bacterial species. The H2T clone is characterised by a 16S rRNA that is 93.8% identical to the claimed sequence and, therefore, deprives claims 1, 2 and 6 of novelty (PCT Article 33(2)).

The 16S rRNA of the *Exiguobacterium acetyllicum* clone disclosed in D4 is 93.6% identical to the claimed sequence and, as a result, also deprives claims 1, 2 and 6 of novelty (PCT Article 33(2)).

Claims 4, 5 and 7 are dependent on claim 1 and, therefore, also relate to any bacterial strain that hybridises to some nucleotides having the sequence ID NO. and also has one of the technical features indicated. It is clear that a large number of the strains described in D1-D4 implicitly have these features. It follows that these claims also lack novelty (PCT Article 33(2)). Novelty could be re-established if the degree of identity to sequence ID NO. 1 were limited to a high degree of identity.

D5 describes a bacterial strain, which has very similar properties to the claimed strain (optimal t° , optimal pH, etc.) but which belongs to the genus *Lactobacillus*.

What is more, D5 describes the use of this heat-resistant strain in the production of lactic acid.

In view of D5, the methods in claims 9-11 do not involve an inventive step (PCT Article 33(3)).

2.2 In light of the documents cited above, the strain claimed in claim 8 is a novel strain of the genus *Exiguobacterium*.

Even though it is characterised by a 16S rRNA which is highly homologous to that of other prior art strains, none of the documents cited suggests the existence of this novel strain.

As a result, claim 8 is novel and inventive (PCT Article 33(1) to 33(3)).

2.3 The subject matter of claims 1-11 is industrially applicable in the field of agriculture science (PCT Article 33(4)).